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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,357	08/27/2003	James Dillon	070050.2882	6693

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EXAMINER	
KHANNA, HEMANT	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/650,357	DILLON, JAMES	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11 and 13-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11 and 13-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to Applicant's remarks filed December 11, 2006. The amendments to claim 1, and 13-16 are acknowledged. Acknowledgement is made of claims 9-10, 12, and 24-30 now canceled.

Claims 1-8, 11, 13-23, are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. (Withdrawn) Rejection of claims 1-23, under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn in view of Applicant's amendments to claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. (Withdrawn) Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Gan et al. (USPN 5,523,316) is withdrawn in view of Applicant's amendments to claim 1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. (Withdrawn) Claims 4-23, rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al (USPN 5,523,316) in view of Calvin et al (Exp. Eye Res. (1997) 65:341-347) and Komiya (Synthesis of Organometallic compounds: A Practical Guide, John Wiley & Sons (UK), 1997, page 35-50) is withdrawn in view of Applicant's amendments to claim 1.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. (New) Claims 1-8, 11, 13-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The specification, while being enabling for methods to reduce oxygen concentration during vitreous surgery, does not reasonably provide enablement for the protection against the development of any and all cataracts in any patient by providing a low-oxygen concentration solution to replace the vitreous humor. The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Nature of the invention. The instant invention is to the protection against cataract development comprising the steps of providing a low oxygen concentration vitreous replacement solution obtained by combination of introducing an oxygen-free gas and

subjecting the solution to a partial vacuum, followed by replacing the vitreous humor with the low oxygen concentration replacement solution.

Breadth of the claims. According to the language of the claims, the steps of providing a low oxygen concentration solution and replacing the vitreous humor with the low oxygen concentration solution will provide protection against the development of any and all cataracts at all times in any patient.

State and un/predictability of the prior art. The claimed subject matter is lacking in predictability wherein it would at best have invariable results regarding the total protection against cataract development at all times. At the time the invention was made, the successful protection against cataract development that resulted from any and all surgeries in any patient, was not routinely obtainable by those skilled in the art. It is presumed that the Applicant's intent is to minimize oxygen concentration that results from the exposure of the vitreous to oxygen during vitreous surgery procedures. Since the success of the former reads on effectively predicting a condition that will result only after the surgical procedures are undertaken, the prevention is not enabled in view of the contemporary knowledge in the art. This is reflected by the findings in a published manuscript. Dillon et al teach that as of 2004, "Oxygen is believed to be one of the potential causative agents for the development of nuclear cataract following vitrectomy" (Abstract, lines 1-2). Further, Dillon et al teach that performing non-vitrectomizing surgery for epiretinal membrane removal reported no post-surgical lens changes (Introduction). Since the only relief from oxygen development occurs in patients who were exposed to oxygen during vitrectomy, one skilled in the art would

conclude that the aspect of protecting against cataract development at all times cannot be expected in view of the knowledge in the art that suggests oxygen being the causative agent for the development of nuclear cataracts in patients following a vitrectomy.

Working examples. Although examples are disclosed in the specification that demonstrate reduction in partial pressure of oxygen post-vitrectomy, no examples indicate the complete protection from cataract development in individuals not needing vitrectomy. Further, no examples are provided that would suggest that the individuals who receive low-oxygen concentration replacement solutions do not relapse into developing cataracts.

Guidance in the specification. The specification provides little guidance regarding practice of the claimed methods to extrapolate means of absolute protection against cataract development at all times. There is a lack of predictability in the art regarding the protection of cataract development by oxygen reduction in any and all patients. The specification does not explicitly replace the vitreous humor with low oxygen concentration solutions to yield a protective endpoint in patients not undergoing vitrectomy.

Amount of experimentation necessary. Given the unpredictability of the art in view of protection by replacing the vitreous humor with low-oxygen concentration solutions, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate with the scope of the claims. Although the applicants have identified an

interesting use providing low oxygen concentration solutions with a role in minimizing the exposure to oxygen during vitrectomies, but essentially all of the work required to ultimately develop a protection method for cataract development has been left for others.

Relative Skill of those skilled in the art. In view of the discussion of each of the preceding seven factors the level of skill in this art is high and is at least that of a Ph.D. or M.D. with several years of experience in the art. As the cited art would point to, even with a level of skill in the art that is Ph.D. or M.D. predictability of the results is not invariable.

In consideration of each of the factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cecilia J. Tsang
Examiner
1600

Hemant Khanna Ph. D.